REMARKS

These remarks are in response to the Office Action mailed April 18, 2003. No claims have been amended. Claims 3 and 35-37 are pending and under examination. Claims 6-34 are withdrawn as directed to a non-elected invention. No new matter has introduced by the present response. Applicants respectfully request reconsideration and allowance of the pending claims.

REJECTION UNDER 35 U.S.C. §§101 AND 112

Claims 3 and 35-37 stand rejected under 35 U.S.C.§§ 101 and 112 for allegedly lacking patentable utility for reasons of record. In particular, the Examiner asserts that the claimed invention lacks either a specific or substantial asserted utility. Applicants respectfully traverse this rejection.

The Examiner asserts that the claimed invention lacks either a specific or substantial asserted utility; however, it appears that the Examiner is really questioning the credibility of Applicants' asserted specific and substantial utility of the claimed invention (namely that as members of the PDZ family, the instant polypeptides are valuable targets for developing pharmaceuticals).

The Examiner states ". . .there is little doubt that, after further characterization, the protein is found to be a member of the PDZ family, the claimed protein would have specific, substantial and credible utility." (See, e.g., the Office Action mailed April 18, 2003, at page 4, lines 8-10). Thus, it appears that the Examiner does not doubt that members of the PDZ family have a specific, substantial, and credible utility; but rather, it seems that the Examiner doubts Applicants' assertion that the claimed polypeptides are indeed members of the PDZ family.

Applicants assert that the polypeptides of the claimed invention are members of the PDZ family. Support for Applicants' assertion can be found throughout the specification as filed (e.g., see the Title) and in the 1.132 Declaration of Shin-Ichi Funahashi dated October 2, 2002. Furthermore, the specification states that members of the PDZ family of proteins interact with PDZ binding transmembrane proteins, a well-established family of proteins reported to play a role in signal transduction, particularly cell proliferation, neural transmission, apoptosis, and malignant conversion. In addition, the specification and 1.132 Declaration of Shin-Ichi

Funahashi submitted on October 2, 2002, provide evidence that the polypeptide of the invention act as PDZ proteins through the various assays. Thus, Applicants' assertion that the polypeptides of the invention are, in fact, PDZ proteins is supported in the application and in the present file history. That assertion cannot simply be dismissed as "wrong". The assertion may be rejected only if the assertion is "incredible", i.e., unbelievable to a person skilled in the art based on the totality of the evidence and reasoning provided. An assertion must be taken as credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. Accordingly, neither (A) or (B), above, is applicable to the Applicants' asserted utility.

In the present application, the Examiner appears to be alleging that the logic underlying Applicants' contention – that the claimed polypeptides are members of the PDZ family of polypeptides having specific and substantial biological significance in terms of signal transduction – is seriously flawed. The Examiner cites to the Skolnick reference to support the position that the "state of the art is such that functional information can automatically be derived from structural information only to a limited extent". Applicants respectfully submit that the Examiner has taken Skolnick's words out of context. Skolnick states "knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein, especially at a detailed biochemical level". In fact, Skolnick endorses the use of sequence homology to identify protein function. (See abstract, lines 4-5: ". . .the goal of converting protein structure to function can be accomplished by traditional sequence motif-based approaches. . ."; also see p. 294, bottom of col. 2: ". . .with only sequence and no structure, researchers usually rely on sequence analysis, a method based on the underlying evolutionary relationships between two sequences." (Emphasis added))

In light of Skolnick's endorsement of the validity of sequence homology to assign function, Applicants submit that the Examiner's burden in demonstrating that one skilled in the art would find Applicants logic to be "seriously flawed" or Applicants' asserted utility to be

"incredible," has not been met. Accordingly, Applicants request review and reconsideration in light of the above comments.

We note that the Examiner seems to have overlooked Applicants' previous arguments that the proteins of the invention possess additional utilities beyond those discussed above. As discussed in the Preliminary Remarks filed with the CPA on January 31, 2003, that the claimed proteins are specifically expressed in liver tissue means they find utility as specific tissue markers. Applicants submit that the invention can be used for tissue typing and measuring tissue expression, a utility that is certainly specific, substantial, and well-established. The Utility Guidelines provide that a "gene probe" or "chromosome marker" is considered to be specific where a specific DNA target is identified. By analogy, the specification teaches that a polypeptide comprising, for example, SEQ ID NO:2 is specifically expressed in liver tissue, thereby providing a specific use to the subject matter claimed. Tissue markers are commonly used in research and diagnostics to identify cell types, as housekeeping markers, and the like. Support for this specific, credible, and well-established utility regarding the use of a polypeptide comprising SEQ ID NO:2 as a tissue marker can be found, for example, at page 7, lines 1-5; Example 5, beginning at page 46, pages 54-55; pages 62-63; and Figures 5, 6, 15, 16, and 19, and corresponding legends at pages 26-32. Accordingly, the polypeptides have a substantial, real-world use that would have been recognized by one of ordinary skill, thereby qualifying as a "well established" utility in satisfaction of the utility requirement.